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DISEASE-PREVENTION CLAIMS AND THE FIRST AMENDMENT:

WHO WILL PROTECT US FROM OUR PROTECTORS?¹

As to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate.²

I. Introduction

The area of disease-prevention claims (health claims) for food poses a broad spectrum of dilemmas that often arise in the food and drug law area and in other regulatory situations. These recurring questions include: How does an agency balance the public's right to information with the agency's desire to prevent consumer deception? Given an agency's broad mandate to protect public health, what type of consumer should it aim to protect with its limited resources? What should an agency do in the face of uncertainty? To what extent, and under what conditions, is informed choice desirable? How much of an agency's role is or should be educational? How should an agency balance consumers' need for information with the problem of information overload?

This paper will attempt to address these and other issues in the context of the arguments over the First Amendment constitutionality of FDA's recently revised treatment of health

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Who Will Protect Us From Our Protectors?, *Obi. News.*, May 1962, at 20.

² *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976).

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claims for food. Ultimately, this paper concludes that the FDA's approach is not only open to attack on First Amendment grounds, but also misconceived from an overarching policy perspective. This paper will ultimately advance an alternative approach which, although not without its own problems, would likely survive scrutiny on First Amendment grounds and also address the major policy questions set forth above.

II. Statutory and Regulatory Background

A. The 1990 Nutrition Labeling and Education Act

In 1990, Congress enacted the Nutrition Labeling and

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Education Act, in order to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded

health claims.⁵ Congress characterized the need for regulation as compelling in a House Report of June, 13, 1990. Some proponents of the statute emphasized that it was intended to alleviate the problems of classifying foods as drugs whenever health claims are made about them and that it was intended to be a more flexible standard than the standards for new drugs.⁶ One proponent of the statute admitted that it was intended to remedy

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The highly contentious debate over dietary supplements is beyond the scope of this paper, as is an in—depth analysis of the FTC's approach to these issues in the advertising context. Rather, the scope of this paper is limited to the FDA's regulation of conventional food labels.

104 Stat. 2353 (Nov. 8, 1990).

58 Fed. Reg. 2478—01.

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See Cong. Rec. H5844 (statement of Congressman Waxman); 58 Fed. Reg. 2478-01.

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the fact that [n]either Federal regulation nor industry efforts have kept pace with scientific knowledge about diet and nutrition. '

The Act adds a new section governing health claims to the

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federal Food, Drug, and Cosmetic Act. A food bearing a health claim must meet the requirements of this new section (403(r)) and

the regulatory requirements of the FDA in order to be excluded from the statutory definition of a drug and all of the regulatory requirements accompanying new drug approval.

It is important to note at the outset that much of the contention in this area surrounds the proper scope of § 403, which states that [a] food shall be deemed to be misbranded (a) If (1) its labeling is false or misleading in any particular The underlying question in much of the debate is the proper scope of the term misleading, since this definition will determine the permissible scope of the FDA's regulations.

B. FDA Regulations

1. Pre-1990 Treatment of Health Claims. - The FDA's regulation of health claims for food has proceeded in stages.⁹ Since 1938, seeing numerous products marketed with unfounded

14±.. (statement of Congressman Madigan).

See FD&C Act § 403(r).

See generally Peter Barton Hutt, Government Regulation of Health Claims in Food Labeling and Adver

41 **Food Drug Cosm. L.J. 3 (1986)**

claims that they would cure various diseases, ¹⁰ the FDA has made it an enforcement priority to prevent false or misleading nutrition claims in food labeling. A main aspect of this strategy has been to classify products for which health claims are made as new drugs that be approved and meet the other statutory requirements for drugs. This approach, however, was not entirely effective, because it only worked if the manufacturer made explicit health claims.

Although the food-drug (and also the food-dietary food) distinction was all-important until very recently, there has been an attempt with the recent statutory amendments to make this distinction less determinative of the level of regulation of a given product. In the face of constantly increasing evidence of the link between proper diet and decreased risk of disease, the FDA must now reconsider its traditional skepticism of all health claims for food.

2. Post-1990 FDA Policy: The Distinction Between Dietary Guidelines and Health Claims.
= **(a) Introduction.** – In an attempt to balance its educative with its protective function, and in order to comply with the 1990 Act, the FDA has set forth a distinction between dietary guidelines, which are to be

¹⁰ For a particularly amusing example, see the advertisement for Grant's Hygienic Crackers in Hutt, *supra* note 9, at 6.

See, e.g., Surgeon General's Report on Nutrition and Health, DHHS (PHS) Pub. No. 88-50210 (1988) (discussing the relationship of diet to health and disease); National Academy of

Sciences, Diet and Health: Implications for Reducing Chronic Disease Risk (1989) (same).

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encouraged, and health claims, which are still forbidden except

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when expressly authorized by the FDA. This Part will examine the FDA's attempt to distinguish the two concepts, and whether this attempt has been successful.

The regulations implementing the 1990 Act define a health claim on a label to include any claim that

expressly or by implication, including third party references, written statements (e.g., a brand name including a term such as heart), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health related condition.

An example of a health claim is X helps reduce the risk of heart disease. Implied health claims are subject to the same rules as explicit health claims, in order to alleviate the prior problem of what to do when the manufacturer does not make explicit health claims. FDA defines implied health claims as:

those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or that would be reasonably understood in the context in which they are presented, to assert a relationship between the presence or level of a substance in the food and a disease or health-related condition.¹⁴

Whether implicit or explicit, FDA identifies two elements of a health claim: first, there must be reference to a substance, defined as a specific food or component of food; and second, there must be reference to a disease or health—related

12 § 101.14(e) (1), (e)(2).

13 21 C.F.R. § 101.14(a) (1).

14 58 Fed. Reg. 2478—01.

condition, defined as damage to an organ, part, structure, or system of the body such that it does not function properly ... or a state of health leading to such dysfunctioning „**15**

FDA identifies certain claims as exempt from the definition of health claim. One group of claims that is allowed is identified as dietary guidance, defined as claims that do not contain both basic elements of a health claim and are therefore not 'health claims.'¹⁶ An example would be a claim that provide[s] guidance about a general food choice or about how to achieve a healthy lifestyle. FDA elaborates in another regulation that claims about the nutritive value of food, defined as those claims relating to a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy, are not considered health claims.¹⁷

(b~ The Fuzziness of the Distinction. – For the most part, the era of the food/drug or food/dietary food distinction as the key to determining a product's level of regulation is behind us, given the 1990 amendments. Yet FDA makes fine distinctions between health claims, both explicit and implicit, which are still forbidden for the most part, and nutritional guidelines,

15 21 C.F.R. §§ 101.14(a)(2), (6).

16 58 Fed. Reg. 2478—01.

17 21 C.F.R. § 101.14(a)(3). Claims relating to diseases that are related to deficiencies in essential nutrients are also exempted from the definition of health claim. See 21 C.F.R. §101.14 (a) (6).

which are appropriate and even encouraged. But what assumptions are reflected in the health claim/health guidance distinction, and is it an improvement? The attempt to distinguish the two is inevitably confusing — perhaps even more than the food/drug or food/dietary food distinctions. The FDA has conceded as much:

[U]se of the term dietary guidance to describe claims that do not constitute health claims is ... confusing because health claims themselves provide a form of dietary guidance. In addition to health claims and dietary guidance, there is a broader class of claims that encompasses all other truthful information about diet and health as well as drug claims.¹⁸

An example may serve to illustrate the dilemma faced by manufacturers in making the distinction. Suppose that a manufacturer wishes to include on his label certain information contained in an AMA report that is favorable toward the main ingredient of its product. The FDA has stated that:

[P]ublicly available dietary information provided to consumers by Federal or private programs and used in food labeling by manufacturers may be either dietary guidance or a health claim depending upon the content of the information and the context in which it is presented in the labeling.

Faced with such nebulous distinctions, it is virtually impossible for a manufacturer to tell whether its particular claim will be approved. Yet although these distinctions are tenuous, they are outcome-determinative under the new regulations, and at stake is whether or not a manufacturer can make the statement at all.

58 Fed. Reg. 2478—01.

III. First Amendment Complications

The FDA's policies toward health claims are especially troublesome when First Amendment considerations are added to the analysis. The FDA's approach is vulnerable to First Amendment attacks on many different fronts. After a brief explanation of commercial speech doctrine, this Part will canvass the various free speech implications of FDA's policies in this area.

A. Virginia Pharmacy and the Emergence of Commercial Speech
Until 1976, commercial speech was an unprotected speech

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category, like libel and obscenity. However, the Supreme Court abandoned this approach in Virginia Pharmacy Bd. v. Virginia

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Consumer Council, when it held that commercial speech that is not misleading (or proposing an illegal transaction) is entitled

to First Amendment protection, though not as extensive as speech nearer the core of First Amendment values.²¹

The Virginia Pharmacy Court had two primary rationales for protecting commercial speech. First, society has a strong interest in the free flow of commercial information; and second, the First Amendment prohibits a state from deciding that consumers would be best protected by ignorance (in that case,

19 See Valentine v. Chrestensen, 316 U.S. 52 (1942).

20 425 U.S. 748 (1976).

21 Id.

ignorance of prescription drug prices) •²² Thus, Virginia

Pharmacy seems to represent a shift in First Amendment emphasis from the traditional right to disseminate information to the right to receive information, though this contention is still controversial.

Qualifications present in the Virginia Pharmacy opinion itself will prove to be pivotal in the health claim area. First, the Court acknowledged that false or misleading advertising can be prohibited; second, the Court hinted that broader regulation of the time, place, and manner of commercial speech might be possible; and third, the Court stated that a strong presumption against prior restraints might not apply to commercial speech.

B. The Status of Health Claims – Commercial or Noncommercial?

Although labeling has been characterized as commercial speech by some courts, no court has directly addressed the speech implications of the regulation of scientific claims on labels. Thus, one of the questions that must be resolved in order to evaluate the First Amendment soundness of the FDA's approach is:

where does scientific speech end and commercial speech begin? Some commentators argue that health claims fall outside of

the commercial speech realm because they convey scientific

²² See also Linmark Assocs., Inc., v. Willingboro, 431 U.S.

85 (1977) (holding that a town's prohibition of For Sale and Sold signs violated the First Amendment because it was an attempt to prevent white flight by keeping the public in ignorance).

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information. Under this reasoning, health claims should receive full First Amendment protection. Thus, the traditional First Amendment analysis would be used: FDA's regulations would be constitutional only if they furthered an important governmental interest unrelated to the suppression of free expression and if the regulations were no more restrictive than necessary. Under such an analysis, even though the prevention of consumer fraud is certainly an important governmental interest, FDA's policies would likely fail as insufficiently narrow to accomplish that objective.²⁴

Another aspect of health claims that lends strength to argument that they are noncommercial in nature is the express Congressional and administrative policy of educating the public in order to promote healthier lifestyle choices. The most commonly used definition of commercial speech is speech that does no more than propose a commercial transaction.²⁵ Yet given the educative purposes of such claims, they appear to do much more than that.

Finally, the Court has said that it is inappropriate to lower the level of First Amendment protection based solely on the

23 See Martin H. Redish, Product Health Claims and the First Amendment: Scientific Expression and the Twilight Zone of Commercial Speech, 43 Vand. L. Rev. 1433 (1990).

24 See id.

25 See Central Hudson, 447 U.S. at 562.

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presence of a profit motive.²⁶ The argument would be that punishing a manufacturer for saying something that could be said in JANA is improper because it effectively exclude[s] one sector

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of society from participating in the public debate. To

overcome these arguments, the FDA would have to argue that speech linking a product to a current public debate can still be

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commercial speech. Nevertheless, if we say that commercial

speech is anything that is intended to enrich the company, then we are perched precariously on an intent standard, which the

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Court has forbidden. Profit motive has never been a useful way to classify speech – one need only think of recording stars and film producers to see the pitfalls of this approach.

There are also those who argue that the commercial/noncommercial speech distinction itself makes little sense. These theorists argue that such a distinction is not in the Constitution, and that the common sense differences identified in Virginia Pharmacy – that commercial speech is more easily verifiable than noncommercial speech, and that commercial speech is more durable than non-commercial speech simply because it is

26 See, e.g., New York Times Co. v. Sullivan, 376 U.S. 254 (1964)

27 Alex Kozinski & Stuart Banner, Who's Afraid of Commercial Speech?, 76 Va. L. Rev. 627, 642 (1990).

28 See Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60

(1983) (holding that drug company mailings containing discussions of important public issues (e.g. venereal diseases and family planning) were nevertheless commercial speech).

29 See Virginia Pharmacy, 425 U.S. at 761 — 65.

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engaged in for profit — are not necessarily accurate and in any case might not lead to the conclusion that commercial speech

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should get less protection than other speech. Professor Tribe

notes that, when the government tries to suppress information based on the possibility that the communicative impact of the message will cause harm, the regulation must survive strict

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scrutiny; on this view, as discussed above, the FDA regulations would almost invariably be struck down.

Even then-Justice Rehnquist's hostility toward commercial speech, as demonstrated in his dissent in Virginia Pharmacy, is helpful in attempting to classify health claims as noncommercial as opposed to commercial speech. Justice Rehnquist argued that the First Amendment was designed to protect discussion of political, social and other public issues, rather than the decision of a particular individual as to whether to purchase one or another kind of shampoo. Nutrition and health are certainly social and public issues, and they are much less trivial than a choice of shampoos.

C. Health Claims as Commercial Speech

Because the Court stated in Virginia Pharmacy that time,

place, and manner restrictions (TPM restrictions) can be somewhat freer when necessary to prevent commercial speech from

30 See Kozinski, supra note 27.

See Laurence Tribe, *American Constitutional Law* (2d ed. 1988) (labeling such cases track 1 cases).

being misleading, FDA has a strong argument that, if health claims are commercial speech, its regulations are proper. Nevertheless, the FDA's treatment of health claims is problematic even under a liberal interpretation of the commercial speech doctrine.

The Virginia Pharmacy Court stated that TPM restrictions are permissible only if they are justified without reference to the content of the regulated speech, ... they serve a significant governmental interest, and ... in so doing they leave open ample alternative channels for communication of information.³² In that case, because advertisements of prescription drug prices were prohibited, the Court held that the proper bounds of TPM restrictions were plainly exceeded, because the statute single[d] out speech of a particular content and [sought] to prevent its dissemination.³³ Along those lines, FDA's regulations are vulnerable, because they attempt to single out only specific kinds of claims about products.

FDA's policies are also open to criticism as invalid TPM restrictions when one focuses on the actual purposes of the regulations, which is one factor of the analysis. Even without these regulations, FDA had the authority to forbid false or misleading claims on labels, and it also has the duty to prevent harmful products. A problem arises, however, when the goal of

³² See Virginia Pharmacy, 425 U.S. 748.

Id.

preventing deception leads FDA to forbid truthful, accurate information. It is an open question whether the harms the FDA is trying to prevent, primarily misinformation about nutrition and waste of money, are sufficient to justify such broad regulations.

FDA's approach is even vulnerable under the four—part Central Hudson test,³⁴ which seems to suggest a type of intermediate scrutiny for commercial speech. Under the Central Hudson test, a regulation of commercial speech is allowed if: (1) the speech is not protected at all (i.e. it's misleading or concerning an unlawful activity); (2) the governmental interest is substantial; (3) the regulation directly advances the governmental interest; and (4) the regulation is not more extensive than is necessary to accomplish the governmental interest; in other words, there is not a less restrictive alternative (LRA). Even if FDA can persuasively argue that all or a majority of health claims are inherently misleading, and even though the government interest in prevention of consumer fraud is substantial, it is still possible to argue persuasively that the regulation is more extensive than necessary and does not directly advance the interest in prevention of consumer fraud.

Although speech that has only the potential to mislead can be

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regulated, when information can be presented either in a

Central Hudson Gas v. Public Serv. Comm'n, 447 U.S. 557 (1980) (involving a ban on promotional advertising by utilities).

~ Friedman v. Rogers, 440 U.S. 1 (1979) (upholding a Texas ban on the use of trade names by optometrists, on the ground that there was a significant possibility that

misleading or a nonmisleading way a statute must attempt to regulate only the misleading format.³⁶ Thus, it is likely that FDA could be required to use the methods it uses in other situations to prevent consumer misconceptions — for example, regulation of the type size or location of health claims on the package.

Some might argue for an even higher level of scrutiny than that of the Central Hudson majority, especially in the case of health claims. For example, in his Central Hudson concurrence, Justice Blackmun argued that, although intermediate scrutiny is fine when speech is potentially misleading or coercive, it gives too little protection against content-based regulation. Justice Blackmun defined a regulation as content—based if it is a covert attempt by the state to manipulate the choices of its citizens

by depriving the public of the information needed to make a free choice. Furthermore, some Justices have expressed the view that strict scrutiny should apply whenever the government suppresses commercial speech and its purpose is to deprive consumers of accurate information concerning lawful activity.³⁷ Under this reasoning, FDA’s attempt to protect consumers from making mistakes in the face of health claims would be struck

trade names will be used to mislead the public). **36** See In re R.M.J.

See Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico, 478 U.S. 328 (1986) (Brennan, J., joined by Marshall, J., and Blackmun, J., dissenting).

down.

In sum, because content—based regulations are generally frowned upon, FDA’s fine distinctions between claims and guidance are quite vulnerable. The FDA can certainly proscribe false and misleading statements in labeling. But when it regulates products differently based on the content of the claims made about them, many would argue that it oversteps the bounds of its mandate of protecting health and safety and enters the realm of impermissible content—based regulation.

IV. A Less Restrictive Alternative:

FDA Non-Endorsement of Health Claims Pending Approval

A. Introduction

Because the underlying tenet of the First Amendment is to counter speech with speech,³⁸ this Part analyzes ways that FDA could avoid the next-to-impossible attempt to distinguish between guidance and claims, and in the process decrease the possibility of consumer misconceptions while at the same time allowing truthful information to reach the public.

B. A Practical Alternative

There is a less restrictive alternative to a nearly complete ban on health claims: rather than broadening its own power and discretion at the expense of personal choice, FDA could require that health claims include a statement that they have not been endorsed by the FDA, and any other statement that it feels is

³⁸ See Kozinski, supra note 27, at 648.

necessary in order to prevent certain common misconceptions. The warning might be along the following lines:

NOTE: THE FDA DOES NOT ENDORSE THE HEALTH CLAIMS MADE BY THIS PRODUCT. INDIVIDUAL HEALTH NEEDS VARY ACCORDING TO AGE, BODY SIZE, AND OTHER FACTORS. PLEASE SEE YOUR DOCTOR BEFORE RELYING ON HEALTH CLAIMS ABOUT ANY PARTICULAR PRODUCT.

Such a warning could be coupled with regulations that would provide only that the health claim must accurately express, in simple terms, the amount of medical data backing the pa
In other words, if a manufacturer wanted to make a claim based on only one study, it could do so if it stated that fact explicitly.

C. The Advantages of This Approach

This approach recognizes the value of informed choice,³⁹ the utility of warnings as demonstrated in areas in which there is even greater danger of harm to the consumer,⁴⁰ and the desirability of individual medical judgment in the areas of

As one journalist put it, [t]rusting David Kessler to decide what health claims you may hear is about as sensible as trusting Pat Robertson to decide what movies you may see. Stephen Chapman, FDA's War Against Health Claims Also Attacks Free Speech, Chicago Trib., Jan. 20, 1994, at 21.

The FDA's gradual inclusion of more nutritional information and more ingredients on labels as health awareness has increased also supports the possibility of informed choice in this area.

40 The FDA's broad interpretation of misleading in this area is inconsistent with its reliance on warnings and informed choice in areas where there is a tangible risk of harm.

health and nutrition.⁴¹ This approach also is more in keeping with the spirit of the First Amendment.⁴² For all of these reasons, this approach is more likely than FDA's current practice to reach a favorable resolution to the policy questions posed at the beginning of this paper.

Of course, this proposal is not without disadvantages. First, the same complications would arise as always in terms of what to do about small packages, small manufacturers, and other special situations. Second, manufacturers might claim that such a warning unduly restricts their promotional activities, since consumers might well assume that a manufacturer making an unendorsed claim is untrustworthy. Third, the requirement of such a warning might intensify the pressure on FDA to loosen its standards of approval. Fourth, on the theory that too much information can be overwhelming and counterproductive, the barrage of claims accompanied by warnings may be too much for

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In similar situations, FDA has argued that consumers might forego medical treatment if they think that they are receiving all of the available information. The difficulty with this argument is that it does not support FDA's current approach. A complete nutritional picture will always be impossible on a label; thus, it is preferable to give consumers as much information as is feasible and then tell them to seek additional advice before relying exclusively on the given material. Some health and nutrition organizations have advocated that the FDA require language on food labels to the effect that diet is only one factor in a person's total health profile, in order to ensure that people will not conclude that exercise, for example, is irrelevant. Such demands, of course, could go on ad infinitum.

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The proposal decreases the free speech concerns by fighting speech with speech rather than prohibiting it. The Supreme Court has in fact expressed a preference for explanations over prohibitions.

many consumers, who will simply tune out all of the messages.⁴³ Nevertheless, the advantages to an approach that would

increase consumer information and choice outweigh these disadvantages. It avoids undermining the public's confidence in the FDA. It allows positive uncertainty (e.g. the chance that a given health claim will eventually be proven to the satisfaction of the FDA) to be on par with negative uncertainty (e.g. the risk of harm as expressed in package inserts and other warnings). It is a more economically efficient way to distribute the information-gathering burden.⁴⁵ It is more realistic than the

See Jacob Jacoby et al., Corrective Advertising and Affirmative Disclosure Statements: Their Potential
46 J. Mktg. 61, 70 (1982).

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To date, FDA has authorized only two health claims: that folic acid can diminish birth defects and that calcium can prevent osteoporosis. So far, claims about the relationship between vitamin E and heart disease are not allowed. FDA's scientific standard is significant scientific agreement, a standard under which many great breakthroughs will go unnoticed.

Suppose the only alternative for a consumer who wants to be informed about promising medical information about nutrition, until the FDA is satisfied, is to inform herself via the scientific journals. Inevitably, she will have to subscribe to more than one journal. Invariably, she will have to read each journal with more than one product in mind — in fact, with each potential element of her diet in mind. It would be much more efficient for a company with only one product or one line of products to canvass all of the literature and attempt to present the latest scientific data in a way that laymen will understand. This manufacturer will be punished if it makes fraudulent claims, and now more of FDA's resources will be available to police such claims. As Cass Sunstein has argued, because informational approaches to regulation leave considerable room for freedom of choice, they avoid the inefficiencies of centralized dictation of outcomes. Cass R. Sunstein, Informing America: Risk, Disclosure, and the First Amendment, 20 Fla. St. U. L. Rev. 653, 660 (1993); see also Stephen Chapman, Scruelching of Facts may be Hazardous to your
Chicago Trib., July 11, 1993, at 3

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FDA’s goal to prevent all health claims that could potentially be misleading, and thus it frees up FDA’s resources for the policing

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of more harmful areas, while at the same time allowing FDA to continue to make progress toward authorizing more health claims.

V. Conclusion

Although the 1990 Act represents an advance over the previous strict prohibition on health claims for food, it nevertheless only allows such claims as specifically authorized by FDA under narrow circumstances. FDA’s interpretation of the statute has created needless confusion over the difference between nutritional guidance and health claims. In this area, it is important to remember that we are talking about safe products and truthful claims as the starting point, since FDA can always prohibit unsafe products and false or misleading claims. Yet the FDA cannot prevent consumers from making mistakes any more than it can prevent all risks in food or drugs. A mistake-free society is no more possible than a risk-free society, but an informed society is within our reach and should be our goal. Thus, although the governments objectives in this area are laudable, its approach can and should be criticized.

(The best way to assure that information gets out quickly is to allow its transmission by the people who stand to profit.).

46 The cost of the new FDA rules has been estimated at between \$1.7 billion over 20 years and \$2 billion for the first year alone. See Sunstein, supra note 45, at 665.